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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/713,386

11/13/2003

William E. Cohn

VIA-41

1618

7590
Jeffrey J. Hohenshell
710 Medtronic Parkway
Minneapolis, MN 55432

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EXAMINER

EREZO, DARWIN P

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/713,386	Applicant(s) COHN ET AL.	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8, 9 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 9 and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The applicant's amendments filed on 12/10/07 has been entered into the application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 8, 9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,395,014 to Macoviak et al. ('014) and in view of US 6,059,757 to Macoviak et al. ('757).

Macoviak ('014) discloses a valved filter device in Fig. 16, wherein the device is capable for use in repair and replacement of cardiac valves, the device comprising: an elongated tube of filter material **642**, said tube being closed at a distal end thereof (the right side of the tube in Fig. 16) and open at a proximal end thereof (the left side of the tube in Fig. 16); and a membrane **644** that is capable of expanding under diastolic

pressure to form a generally parabolic cone substantially blocking flow of blood therethrough, and compressible under systolic pressure to form a substantially non-flow blocking configuration to permit flow of blood therethrough.

Macoviak ('014) is silent with regards to a valve seating retaining ring fixed on the proximal end of said tube; wherein the membrane is tethered to the open end of said tube the valve seating retaining ring at multiple spaced apart fixation points around the circumference of ring.

However, in col. 10, ll. 55-60, Macoviak ('014) states that the valve membrane assembly suitable for the invention also includes the valve membrane assembly of the '757 reference. The '757 reference discloses a valve membrane assembly comprising a valve seating retaining ring (element 20 in Fig. 1, 1(a)-1(b)); a membrane **22** attached to the retaining ring at multiple spaced fixation points around the circumference of the ring; wherein the retaining ring is attached to a catheter via elements **18**. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to use the valve membrane assembly of the '757 reference in the '014 reference since Macoviak discloses that the device of the '014 reference is capable of using the valve membrane assembly of the '757 reference.

The above combination is still silent with regards to the retainer ring being fixed on the proximal end of the elongated tube. Instead, the device shown in Fig. 16 of the '014 reference discloses the valve assembly being adjacent to the open proximal end of the elongated tube. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to integrate the retainer ring with the elongated

tube since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965). One could easily integrate the retainer ring with the elongated tube without destroying the function of the device since the arrangement of the valve assembly is already disclosed as being adjacent to the open proximal end of the elongated tube.

(claim 9) Macoviak ('014) discloses a catheter **646**.

(claim 11) Macoviak ('014) discloses another embodiment in Fig. 8 of a device having skeletal members for supporting the tube. One of ordinary skill in the art would have found it obvious to modify the embodiment of Fig. 16 to include skeletal members as shown in Fig. 8 because the skeletal members help support the tube in the open configuration.

(claim 12) The modified device of Macoviak ('014) will have the membrane attached to the inner surface of the valve seating retaining ring, as shown in the '757 reference.

(claim 13) The modified device of Macoviak ('014) to have the retainer ring be integral with the open end of tube will inherently cause the ring and the open end of the tube to expand and compress if the membrane expands and compress.

Response to Arguments

5. Applicant's arguments with respect to claims 8, 9 and 11-13 have been considered but are moot in view of the new ground(s) of rejection. The applicant has amended independent claim 8 to include the limitation of claim 10, but has also included

the additional limitation of "...spaced apart fixation points around the circumference of ring...", thus requiring new consideration. Furthermore, the amendment has also changed the scope of the claimed invention for the remaining dependent claims which required new considerations and an updated search and new rejections.

6. The applicant's cancellation of claims 5-7 has obviated the rejections under obviousness double patenting.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/
Primary Examiner, Art Unit 3773